Massachusetts Department of Public Health

State Laboratory Institute

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Mycobacteriology (TB) Laboratory Update

In the coming months the Mycobacteriology Laboratory at SLI will be implementing several improvements in services. These changes, as well as current services provided by the laboratory, are described below.

Recent and Upcoming Service Improvements

Remote Order Entry and Results Inquiry/Reporting: A virtual private network (VPN) system for remote order entry and results inquiry/reporting is being developed to facilitate and expedite communications with the TB laboratory. The system will be piloted at 3-5 hospital laboratories in Spring 2004, and will then be rolled out to other laboratories as quickly as possible. No additional software is required for using this system, and SLI will provide initial training and subsequent support services. This system will initially feature capabilities for the basic functions of order entry and results inquiry/reporting for TB specimens only, but will eventually expand to a secure Internet-based system that provides access to all tests performed at SLI. Until a site has been brought into the VPN, the TB Laboratory will continue the routine practice of reporting all positive test results immediately by phone, and mailing hard copies of all preliminary and final reports to the submitting site.

Extended Hours: The TB laboratory will be extending its days of operation from M-F to M-Sat., so that AFB smear results for specimens received late on Fridays can be available within 24 hours.

Improved Client Service: In order to facilitate rapid response to all client inquiries, requests and concerns, the TB laboratory has established a Client Service Representative (CSR) position. The CSR will directly address issues relating to services, test status/results and billing, and will direct specific laboratory, clinical, and epidemiologic inquiries to the appropriate consultants.

Courier Service: To decrease the average time for specimen delivery, SLI has recently instituted a courier system for delivery of TB Laboratory specimens via UPS. This courier service, which also allows for tracking of packages, is free and available statewide to all Massachusetts providers who submit specimens to the SLI TB Laboratory. Please contact Kristen Pribeck for additional information (see contact below.)

Laboratory Tests and Services

Testing services provided by the SLI Mycobacteriology Laboratory are briefly described below. Detailed descriptions are found in the *SLI Manual of Laboratory Tests and Services*, available on line at: http://www.state.ma.us/dph/bls/manual/blsmts.htm.

Detection: Detection of mycobacteria is based on smear microscopy, bacteriological culture and, for the species of *M. tuberculosis* complex, the MTD test. AFB smear microscopy is performed using fluorochrome staining, with a turn-around-time (TAT) of <24 hours for 95% of specimens received. Cultures are grown on three media (LJ, 7H11 and MGIT™) to assure higher recovery rates

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SLI Test Request Form: Evaluation and Update

A high priority goal of the SLI strategic plan is to provide test requests, inquiries and reporting through a secure web-based system. Progress towards this goal is proceeding and we expect to introduce the system in 2005. One of the early phases of this plan was to develop a "universal" form for test requests. The first step of this effort was the introduction of a single form for requesting tests for infectious diseases, SLI Requisition SS-SLI-1-03 (see page 4), which replaces more than 15 disease-specific forms. The introduction of this form has been a success in the first ten months of its use. SLI QA monitors requisitions received at SLI to identify any problems with test request submissions, and will make changes where appropriate. SLI QA also works with laboratory managers and supervisors to address specific issues as they arise. We are currently reviewing several

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for various mycobacterial species. The MGIT™ (BD BBL™) liquid media also provides a faster growth rate for the majority of *M. tuberculosis* cultures. The Mycobacterium Tuberculosis Direct test (MTD, Gen-Probe®), a rapid nucleic acid amplification technique, is performed directly on the first smear-positive respiratory specimen from new patients (and smear-negative specimens by request). This test detects *M. tuberculosis* complex organisms within one working day (typically 2-4 weeks before conventional culture results become available.)

Identification: Several methods are used for identification of mycobacterial species. AccuProbe (Gen-Probe®) testing of positive cultures identifies *M. tuberculosis* complex, *M. avium* complex, and *M. kansasii* within 24 hours from detection of visible culture growth. Conventional biochemical methods are used for identification of isolates that cannot be identified by the probe assay. Except in rare instances, the TB Laboratory is able to identify most mycobacterial species. Occasionally, some unusual mycobacterial species are sent to CDC, Atlanta, GA for identification. The TB Laboratory reports these results as soon as they are received from CDC.

Drug Susceptibility Testing (DST): The BACTEC™ 460 TB radiometric system (BD) is used for DST for "first line" drugs (isoniazid, rifampin, streptomycin, ethambutol and pyrazinamide), with an average TAT of 5 – 7 days from detection of bacterial growth for susceptibility results. The agar plate proportion method is used for determining susceptibility to the "first line" drugs plus "second line" drugs (cycloserine, ethionamide, PAS, capreomycin, kanamycin, amikacin, ciprofloxacin, and levofloxacin), as well as three concentrations of isoniazid and two concentrations of streptomycin.

Reporting: All positive findings, including AFB smear and culture results, and all DST results are reported to the providers by phone as soon as they become available. Hard copies of final reports are delivered by mail.

Other Diagnostic Services: RpoB gene DNA sequencing, for rapid detection of rifampin-resistance in smear-positive specimens or grown cultures, is available upon request to the TB Laboratory Director (see contact below.) RFLP and VNTR methods, used to type *M. tuberculosis* isolates to determine routes of transmission or to identify specimen cross-contamination, are also available upon request to the TB Laboratory Director. Case clustering analyses are performed by RFLP and VNTR with approval from the TB Prevention and Control Program (see contact below.)

TB Case Management and Contact Investigation

The TB laboratory works closely with the Massachusetts Division of TB Prevention and Control, which ensures appropriate clinical and epidemiologic follow-up of all TB cases in the State. These services include visits to State-funded TB clinics for diagnostic evaluations and treatment, nursing case management for all suspect and confirmed cases, nursing and medical consultation, outreach, directly observed therapy, patient incentives, and contact investigation. There is a direct electronic link between the TB Laboratory and the TB Division, which expedites case management by facilitating immediate reporting of all TB Laboratory results to the Division and its case management team, and by immediately alerting providers of priority results, such as positive sputum smears or drug-resistance.

Expert Consultation/Contacts

The TB laboratory and the Division of TB Prevention and Control provide access to a staff of laboratory, clinical and epidemiologic consultants, who are available to help with any questions or problems that may arise during the course of patient diagnosis, management and follow-up. Contacts include the following:

Mycobacteriology (TB) Laboratory
Main Number: 617-983-6374
Paul Elvin, Laboratory Supervisor: 617-983-6381

Client Inquiries
Scott Mahoney, Client Service Representative: 617-983-6907, pager 617-675-2332, e-mail: scott.mahoney@state.ma.us

Special Testing Services and Consultation
Alexander Sloutsky, Ph.D., Director, Mycobacteriology Laboratory: 617-983-6370

Laboratory Management Services
Linda Han, M.D., M.P.H., Associate Director, State Laboratory Institute: 617-983-4362

Massachusetts Division of TB Prevention and Control
John Bernardo, M.D., Medical Director: 617-983-6970, e-mail: jbernardo@lung.bumc.bu.edu
Sue Etkind, Director: 617-983-6970

Courier Service
Kristen Pribeck, Administrative Assistant: 617-983-6212

SLI Test Request Form: Evaluation and Update

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recommendations for clarifying certain fields in the requisition form that have been reported to be problematic. This requisition form will be the basic template for data entry once the development of the application for remote test order entry begins. It is therefore very important to us that you provide feedback on any aspect of the use of this form at your site. Comments and questions regarding the SLI test requisition form should be sent to: State Laboratory Institute, Peggy DiNatale, Quality Assurance Department, 305 South Street, Jamaica Plain, MA 02130, (617) 983-6243, email: margaret.dinatale@state.ma.us.

Important Points to Remember – You can help us by taking note of these items that have been identified as common problems.

Legibility: Requisition legibility is the most common problem encountered. This is an issue that will be readily addressed by electronic submission of test requests, which will be introduced in the future. Until then, we ask that everyone help us be more efficient in providing timely test results by paying attention to the legibility of information provided on forms. When information is illegible, lab staff must call the submitter, which is inefficient for both the submitter and SLI staff. If a stamp is used to identify the facility to which the results are to be sent, please ensure that the stamp is complete and legible. We receive many stamped requisitions in which portions of the provider name and/or address are missing.

Written and verbal test reports: The facility named in Field #1 of the requisition form is the facility to which results will be mailed. It is important to remember that, pursuant to CLIA and HIPAA regulations, written reports will be routinely sent only to this address. Also, verbal results can only be given to representatives of the entity named in Field #1, Provider Information, or to the Physician/Contact named in Field #3. When requisitions are completed at primary care sites and sent to a third party laboratory for referral to SLI, the primary care site will be the only facility authorized to receive both verbal and written results if it is listed in Field #1, Provider Information. Alternatively, if the third party laboratory is listed in Field #1, Provider Information, without the primary care physician being listed in Field #3, Physician/Contact, then both verbal and written results can only be released to the third party laboratory. In this case, the primary care physician would have to contact the third party laboratory to receive results.

Field #3, Physician/Contact: This field should contain the name and phone number of the ordering provider. This is the person who will be contacted by phone in the event of a critical, positive, or abnormal test result, or any other situation requiring immediate contact with the patient's physician.

Field #2, Patient Information, and Field #4, Date of birth of the patient: Complete information regarding the residential address and date of birth of the patient is required during follow-up of reportable diseases by epidemiologists in the Bureau of Communicable Disease Control. In addition, such information may be critical to future patient care.

Field #5, line 2, Disease suspected: This field is problematic particularly for submissions of viral serology specimens. This field should contain only the disease or agent that is most likely the cause of the patient's illness. If more than one agent is suspected, this field should contain a limited listing of only the most likely agents. Confusion and delays arise when this field is completed with long lists of agents to be ruled out, in which case SLI staff must call the provider to determine which tests are indicated.

HIPAA and Requests for Test Results

The State Laboratory Institute has updated its procedures for the release of test results to clinicians via telephone or fax. These procedures are based on SLI policy and follow the requirements described in the Department of Public Health HIPAA Confidentiality Policies and Procedures Manual. The procedures were piloted for three months by the Bacteriology Laboratory before SLI-wide implementation in January 2004.

Before a verbal or written test result can be released to a clinician or laboratory, SLI must verify that the caller represents the ordering provider/physician listed on the requisition submitted with the specimen. This requirement underscores the importance of having complete, legible information on the requisition form, since we cannot release results on request unless we can verify the information in Field #1, Provider Information, and Field #3, Physician/Contact. It is important to remember that written reports will be routinely sent only to the address listed for the entity named in Field #1, Provider Information. Also, verbal results will be routinely given only to representatives of the entity named in Field #1, Provider Information, or to the Physician/Contact named in Field #3.

Faxed or written requests for test results must include (1) the name of the ordering provider (from Field #1 of the requisition) on company letterhead, fax page header, or laboratory information system (LIS) printout, (2) the name and title of the person requesting the results, and (3) all relevant patient information (name, date of birth, specimen collection date and accession number, test requested, and ordering provider).

If your facility is experiencing any problems related to the release of test results, please contact Dina Caloggero (617-983-6601) or Peggy DiNatale (617-983-6243), the SLI HIPAA liaisons.

Specimen Submission Form

STATE LABORATORY INSTITUTE
305 South Street
Jamaica Plain, MA 02130-3597
PLEASE PRINT **Tel. 617-983-6200** DO NOT ABBREVIATE

Do not use this space

General Form

1. PROVIDER INFORMATION

Name

Address: No./Street

City/Town State Zip Code

Phone Number: ( )

2. PATIENT INFORMATION

Name: Last First Initial

Address: No./Street/Apt #

City/Town State Zip Code

Patient ID No:

3. PHYSICIAN/CONTACT

Phone Number: ( )

4. Sex ☐ M ☐ F ☐ Other **Date of Birth** (mm/dd/yyyy) / /

Ethnicity ☐ Hispanic or Latino ☐ Not Hispanic or Latino

Race (check one)
- ❑ American Indian or Alaska Native
- ❑ Asian
- ❑ Black or African American
- ❑ Native Hawaiian or Other Pacific Islander
- ❑ White
- ❑ Other

5. TEST REQUESTED:_____

DISEASE SUSPECTED:_____

Date of Onset (mm/dd/yyyy)_____

Reason: ☐ Symptomatic ☐ Confirmation ☐ Surveillance
☐ Contact ☐ Test of Cure

For: ☐ Identification ☐ Isolation ☐ Typing
(----------Complete Section 7----------)

☐ Serology (Complete Section 6)

❑ Other (specify)_____

6. SEROLOGY:

☐ Serum ☐ Spinal Fluid

☐ Acute ☐ Convalescent ☐ Late Convalescent

Date Collected (mm/dd/yyyy) _____/_____/_____

7. CULTURE: Specimen submitted is: (mm/dd/yyyy)

❑ Original Material. Date Collected: _____/_____/_____

❑ Subculture. Date Subculture Made: _____/_____/_____

❑ Has specimen been treated? ☐ Yes ☐ No
Specify Method _____

Source of Specimen:

- ❑ Anal Canal
- ❑ Blood
- ❑ Cervix
- ❑ Gastric
- ❑ Nasopharynx
- ❑ Pharynx
- ❑ Plasma
- ❑ Serum
- ❑ Spinal Fluid
- ❑ Sputum
- ❑ Stool
- ❑ Throat
- ❑ Urethra
- ❑ Urine
- ❑ Vulva (child)
- ❑ Bronchus (site)_____
- ❑ Wound (site)_____
- ❑ Exudate (site)_____
- ❑ Tissue (specify)_____
- ❑ Other (specify)_____

8. FOR VIRUS SEROLOGY, VIRUS ISOLATION and TESTS LISTED AS CDC SEROLOGY or CDC CULTURE IN THE SLI MANUAL OF TESTS and SERVICES.

Symptoms and Duration_____

_____

Travel History (and dates of travel)_____

Animal/Arthropod Contact (specify) _____

Previous Laboratory Results_____

Relevant Immunizations (give dates) _____

Additional Information:_____

_____

INSTRUCTIONS: If a section does not apply to a given situation, write N/A (not applicable). For more information on SLI testing, see the SLI Manual of Tests and Services at http://www.state.ma.us/dph/bls/manual/Blsmts.htm

FORM-SS-SLI-1-03

Massachusetts Chemical Terrorism Response Laboratory

The Centers for Disease Control and Prevention (CDC) provided funding to each state public health laboratory for Chemical Terrorism (CT) Laboratory Preparedness for federal fiscal year 2004 (Sep-Aug). Through this commitment, CDC seeks to establish the infrastructure for a comprehensive Chemical Terrorism Laboratory Response Network. Three levels of laboratory capacity with different amounts of funding were established. Level I laboratories must provide clinical sample collection and handling services, however they are not required to perform laboratory analyses for CT agents. Level II laboratories must develop the capability to analyze certain CT agents in clinical samples. Level III laboratories provide surge capacity to the CDC for the analysis of the most hazardous chemical terrorism agents, as well as meeting the requirements of Level I and Level II laboratories. In previous years, five states received Level III funding, but there was no Level I or Level II funding available. Massachusetts recently applied for and received funding to establish a Level II Chemical Terrorism Response Laboratory (CTRL).

In accordance with the requirements of the CDC cooperative agreement, the Massachusetts CTRL must accomplish two objectives. The first is to build laboratory capability and capacity for the analysis of clinical samples for heavy metals and cyanide, and the second is to develop a comprehensive emergency response plan. In order to analyze clinical samples for chemical terrorism agents, the CTRL must renovate laboratory space for the installation of a gas chromatography mass spectrometer and an inductively coupled plasma mass spectrometer, hire a CT laboratory supervisor and two chemists, train staff on CDC analytical methodology and successfully complete proficiency testing. Developing an emergency response plan involves establishing a CT response workgroup, producing protocols for the collection, handling and transport of clinical specimens, and strengthening coordination with emergency response agencies. In Massachusetts, the SLI will be working closely on CT preparedness with the Department of Fire Services, State and local Police, FBI, USEPA, FDA, the Massachusetts National Guard Civil Support Team, and Massachusetts hospitals and clinics.

In the coming months, the Massachusetts CTRL will be incrementally increasing its capability and capacity to respond to a chemical exposure event. In the case of a suspect or actual chemical exposure event, whether deliberate or accidental, the CTRL will work with emergency response agencies to detect and identify the chemical agent, and provide technical assistance to limit further exposures. The CTRL will test clinical samples from exposed and potentially exposed individuals for analyses. The clinical samples may be tested for agents, such as cyanide, arsenic and other heavy metals depending upon the diagnostic or forensic information available. Should a clinical diagnosis or other information suggest chemical agents that the CTRL does not have the capability to analyze, such as sarin, the CTRL will forward clinical samples to the CDC or a designated Level III laboratory for analyses. In addition to clinical samples, CTRL may test environmental samples for suspect analytes, and/or forward samples to the USEPA, Massachusetts Department of Environmental Protection or military laboratories for analyses.

SARS Testing at MSLI

Severe acute respiratory syndrome (SARS) is a viral respiratory illness caused by a coronavirus, SARS-associated coronavirus (SARS-CoV). The Centers for Disease Control and Prevention (CDC) has developed and made available to state public health laboratories two sensitive and highly specific diagnostic assays for SARS-CoV: the SARS-CoV enzyme immunoassay and the SARS-CoV reverse transcriptase PCR assay. The SLI has successfully completed CDC proficiency testing for both tests, and will perform both tests on specimens collected from patients with suspected SARS after individual case review and approval by the MA Department of Public Health Epidemiology Program staff (617-983-6800). All specimens with positive results will be forwarded to CDC for confirmation.

To identify other potential causes of respiratory disease, SLI will also perform rapid antigen testing for respiratory syncytial virus (RSV) and influenza A and B. CDC guidelines for interpretation of SARS-CoV test results, and guidelines for collection, handling, and testing of suspect SARS specimens, are available at http://www.cdc.gov/ncidod/sars/.

Newsletter Editor: Marcia Stowell, EdM, MT(ASCP). Please contact the editor for comments and inquiries, additions and changes to the mailing list, or to be added to the electronic mail list. Phone: 617-983-6283, E-mail: sli.newsletter@state.ma.us. Please visit our Web Site for the electronic version of this newsletter and other information about the State Laboratory Institute: www.state.ma.us/dph/bls.

Laboratory Training Activities

Agents of Bioterrorism - Level A Training for Sentinel Laboratory Partners – State Laboratory Institute, Boston, MA:
Fee: no charge. Pre-registration required. Call State Training Coordinator (see contact information below).
Upcoming schedule for 2004: April 23, May 21, Sept. 24, Oct. 22, Nov. 19.

Packaging & Shipping Diagnostic Specimens & Infectious Substances – State Laboratory Institute, Boston, MA:
Fee: no charge. Pre-registration required. For program description and registration, please visit the following Web site: www.state.ma.us/dph/bls/labsite.htm. Upcoming schedule for 2004: May 19, June 9, July 21, Sept. 15, Oct. 6, Nov. 17.

State Laboratory Training Coordinator, *Garry R. Greer, BS, (617) 983-6608, E-mail: garry.greer@state.ma.us.*
For a list of NLTN courses and resources sign on to the Web at http://www.phppo.cdc.gov/nltn.

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